MEMORANDUM

TO: Commissioner Ferguson and Members of the Public Health Council

THROUGH: Nancy Ridley, Assistant Commissioner, Bureau of Health Quality Management

FROM: Paul Dreyer, Director, Division of Health Care Quality

DATE: September 23, 2003 (Issued September 16, 2003)

RE: Request for Final Promulgation of Proposed Amendments to the Hospice Program Licensure Regulations (105 CMR 141.000) - Effective October 10, 2003.

Background

In August 2002, Chapter 283 of the Acts of 2002 was signed into law (see Attachment A). Chapter 283 amended Massachusetts General Laws, Chapter 111, section 57D, which governs the licensure of hospice programs. The amendments directed the Department to establish regulations to license up to six inpatient hospice facilities that would be directly owned and operated by a hospice program. Currently, hospice inpatient care, which offers hospice patients symptom management and pain control that cannot be accomplished in the home setting, is provided through contract arrangements between hospice programs and hospitals or long term care facilities. Some hospices have experienced problems in securing contracts or obtaining inpatient placements when needed. This situation, coupled with the goal of providing better end of life care with staff trained in the hospice philosophy, prompted the hospice community to propose the amendments to the statute governing hospices that would allow them to provide their own inpatient services.

The statute provides that through 2006, a limited number (up to 6) of hospice inpatient facilities directly owned and operated by a hospice program may be approved by the Department. Pursuant to the statute, the Department will conduct an interim review of the status of the licensure of these inpatient services in 2004. In 2006, the Department will determine, based on a review of the experience of the approved inpatient programs, whether there should be additional or fewer hospice inpatient facilities.

Changes in the language of the statute also expanded on the definition of a hospice program and clarified the hospice programs' mission and responsibility to provide continuity of care through the full range of settings: at home, in the community and in facilities. Finally, language was added to explicitly prohibit a hospice program from operating in Massachusetts or using the words "hospice" or "hospice program" without a license. These changes have been incorporated in the proposed amendments.

Hospice Work Group

The Hospice Work Group (see Attachment B) met 5 times in 2003 to develop the proposed amendments.

Highlights of Proposed Amendments

Freestanding AIDS Hospice Facility

The Hospice Program Licensure Regulations at 105 CMR 141.000 have not been substantially revised since 1988. The 1988 amendments established licensure requirements for freestanding AIDS hospice facilities. One freestanding AIDS hospice facility opened under these regulations in 1989. Improvements in AIDS treatment, patient preference to not be segregated in a facility solely treating AIDS patients and improved home-based care resulted in decreased utilization of the facility. The Hospice at Mission Hill closed in 1997. The regulations regarding the freestanding AIDS hospice facilities have been deleted in the proposed amendments.

Licensure Requirements for Hospice Inpatient Facility

Under the proposed amendments, a hospice inpatient facility directly owned and operated by a hospice program must:

- Meet the Medicare Conditions of Participation for hospices that provide inpatient care directly (42 CFR 418.100). The Conditions of Participation include requirements regarding nursing services, physical plant, disaster preparedness, federal, state, and local health and safety regulations, fire protection, linen supply, infection control, meal services, pharmaceutical services, medication administration and drug storage and disposal;
- Meet additional physical plant requirements (see 105 CMR 141.299: Appendix A);
- Have an RN on duty 24 hours a day supervising nursing care and nursing personnel;
- Designate an RN as the Director of Nursing (or an equivalent title) who has administrative authority, responsibility and accountability for the functions, activities and training of nursing services staff;
- Have additional licensed and other staff to meet the patients' care needs;
- If admitting pediatric patients, provide medical and service equipment that is age and size appropriate; and
- Develop infection control policies, including the proper disposal of infectious waste.

Prerequisite of Licensure of a Hospice Inpatient Facility

Under the proposed amendments, only hospice programs that have been licensed for at least two years prior to the effective date of the amendments may apply to add a hospice inpatient facility to their license.

Application

Under the proposed amendments, hospice programs that have been licensed for two years prior to the effective date of the amendments may submit an application to the Department on or after 90 days from the effective date of these amendments and until six applications are approved.

The information to be included in the letter of application will be detailed in a memorandum that will be sent to all hospice programs upon promulgation of the amendments. The requested information will include, but not be limited to, a description of the inpatient facility (e.g., location, number of beds, anticipated renovation/construction and related costs, etc.), financial projections for the operation of the facility, projected patient volume and payer mix information, as well as documentation of ownership or a valid lease agreement for the proposed site of the hospice inpatient facility.

Additional Requirements for Hospice Programs (not specific to an inpatient facility)

In addition to licensure requirements for hospice inpatient facilities, the amendments include revisions that apply to an entire hospice program, not just an inpatient facility. These include:

- If the hospice program admits a pediatric patient:
  à a registered nurse with clinical pediatric training and experience shall coordinate the implementation of the plan of care for each pediatric patient, and
  à the hospice shall provide age and size appropriate drug administration and dosing.
- A hospice program must obtain a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver if it intends to perform any laboratory tests, e.g., glucose monitoring or fecal occult blood test. (The CLIA requirements were not in effect when the hospice regulations were revised in 1988.) One certificate may cover tests performed in patients' homes and in a hospice inpatient facility. The Department will issue a memorandum with more information about the laboratory tests that may be performed by a hospice program under the Certificate of Waiver.
- No drug or medication that has been removed from the market by the Food and Drug Administration shall be stocked or administered by a hospice.
- Hospice staff shall have access to references for drug interaction and drug dosing.

Incident reporting

These amendments include language regarding incident reporting, patient abuse, mistreatment and neglect or misappropriation of property, and grievance procedure requirements consistent with the requirements for other health care facilities/providers. Refusal to permit inspection or photocopying of records by the Department has been added as a cause for denial, revocation or refusal to renew a license.

Public Hearing and Comment

The Department conducted a public hearing on July 30, 2003 and accepted comments through August 6, 2003. Three people attended the hearing. The President of the Hospice and Palliative Care Federation of Massachusetts presented testimony. During the comment period, two individuals representing VNACare Network, Inc., Worcester and Hallmark Health Hospice, Malden submitted letters supporting the Hospice and Palliative Care Federation's recommendations. The following summarizes the comments and the Department's response.

1) 141.204 Required Patient Care Services (A): The Federation reiterated its support for the language included in the proposed amendments that emphasizes, consistent with Medicare certification standards, that a licensed hospice program must provide hospice services throughout the range of community and institutional settings. In order to meet the federal definition of a hospice program and be eligible for Medicare certification and reimbursement, an entity that operates both a licensed health care facility and a hospice program must document through patient records that the hospice program serves patients in the community, not just inpatients of the licensed health care facility.

Response: No change required.

2) 141.204 Required Patient Care Services (E) Social Work Services: The Federation recommended that the social worker licensure categories that qualify to provide social services for a hospice program be in included in this section.

Response: The licensure categories are in the Definitions section of these regulations, but have been inserted here as well, as recommended.

3) 141.204 (H) Inpatient Care (4)(c)(ii): The Federation recommended that the words "on site" be added to clarify that the on duty registered nurse must be in the facility, not on call, 24 hours per day.

Response: The Department has added the words "in the hospice inpatient facility", consistent with language in the Medicare Conditions of Participation guidelines at 42 CFR 418.100(a).

4) 141.299 General Standards of Construction. Required Supporting Elements - Nursing Care Units: The Federation recommended the elimination of the requirement of a 'drinking fountain' because it is "no longer considered a sanitary way of providing public drinking water when other means such as water coolers and disposable cups are available".

Response: The Massachusetts plumbing code requires drinking fountains in a health care facility. The Architectural Access Board regulations at 521 CMR 36.1 state that "drinking fountains shall include water coolers". The Department therefore has added the words "or water cooler" to acknowledge other acceptable means of providing drinking water.

5) 141.299 General Standards of Construction. Patient Bedrooms - Nursing Care Units (C): The Federation recommended that the following sentence be deleted: "Beds shall be spaced at least three feet from any other bed".

Response: The Department has deleted this sentence because all rooms in the hospice inpatient facility will be private rooms.

6) 141.299 General Standards of Construction. Patient Bedrooms - Nursing Care Units (G): The federation recommended the deletion of "with a minimum of one drawer per patient ".

Response: The Department has deleted this phrase because it is unnecessary; there will only be one patient in each bedroom.

7) 141.299 General Standards of Construction. Medicine Room/Closet -Nursing Care Units (A): For the location of the medicine room/closet, the Federation recommended substituting "in close proximity to" for "directly off" the nurses' station.

Response: The Department has deleted "directly off or immediately adjacent" and substituted "in close proximity". The revised sentence now reads: "A separate, locked medicine room/closet shall be provided in close proximity to each nurses' station."

8) 141.299 General Standards of Construction. Storage Areas - Nursing Care Units. Utility Rooms and Linen Storage Areas: The Federation recommended revising the specific requirements of soiled and clean utility rooms and equipment as well as a central clean linen area and soiled linen room, stating that some of the equipment is unnecessary (e.g., bedpans are now disposable, therefore the washer/sanitizer is unnecessary) and patients may have linen and personal laundry done individually and stored in his/her room. They recommended the following language be substituted: "Soiled and clean utility areas will be separate from each other with appropriate cleaning equipment and storage facilities."

Response: The Department has not revised the language regarding utility rooms or linen storage. Although some facilities may have patient linen and laundry done individually, not all will. In either case there is a need for additional (backup) linen and a place to store it, particularly in a larger facility, as well as a room in which to keep soiled linen to avoid odor in the patient room. A smaller facility could request a waiver. The Department deleted the requirement of a bedpan washer and sanitizer in the soiled utility room.

9) 141.299 General Standards of Construction. Office Space (A) Administrative Offices (2): The Federation recommended that only separate space, not offices, is needed for the Administrator and Director of Nurses.

Response: For the purposes of privacy, the Department has maintained the requirement of office space, but reduced it to "at least one office" instead of "separate offices", to be used by the Administrator and Director of Nurses.

10) 141.299 General Standards of Construction. Nourishment Kitchen: The Federation recommended that a microwave oven be added as an alternative to the surface cooking unit.

Response: The Department has added "or microwave oven".

11) 141.299 General Standards of Construction. Meal Service Facilities (C)(1)(c): The Federation recommended that the requirement of a separate service sink for washing pots and pans should be eliminated; that the sink for food preparation could also be used for washing pots and pans.

Response: The Department has not revised this section. Depending on the size of the facility, a separate service sink would be necessary. Smaller facilities could request a waiver.

12) 141.299 General Standards of Construction. Corridors: The Federation recommended that the corridor width for areas used primarily by patients should not be less than five feet instead of eight feet, stating that this would be more consistent with a home-like atmosphere. The Federation also recommended that the same corridor allowances for conversions of buildings previously licensed as inpatient health care facilities should be available to hospice residences that convert a portion of their space to a hospice inpatient facility. [Buildings previously licensed as inpatient health care facilities may maintain existing corridor widths as long as they are not less than four feet wide, and still be Medicare certified.]

Response: The eight foot corridor requirement is consistent with the Life Safety Code of the National Fire Protection Association, which all new Medicare certified hospice inpatient facilities would have to meet. Changing the corridor width requirement in the Massachusetts licensure regulations would not eliminate the Life Safety Code requirement for federal Medicare certification. There is, however, under the federal regulations, the alternate Fire Safety Evaluation System (FSES) process available to facilities seeking a waiver of any specific provision of the Life Safety Code, such as corridor width.

The Department has not revised the licensure language to allow converted hospice residence space to maintain its existing corridor widths. The current licensure language is consistent with the Life Safety Code requirements, which grandfather buildings previously licensed as inpatient health care facilities. Changing the licensure regulation language would not change the Life Safety Code requirements.

Miscellaneous corrections:

1) 141.299: General Standards of Construction. Utility Rooms - Nursing Care Units: Inserted "(A)" before Soiled Utility Room and "(B)" before Clean Utility Room.

2) Correction of typographical error in existing regulations:

141.299 General Standards of Construction. Corridors (B): "Handrails shall be firmly anchored and shall not project more than 3 ½ inches into the required minimum width of the corridor…" (Some editions of the licensure regulations dropped the '½'.)

3) 141.299 General Standards of Construction. Electrical: Night Lights (A) and Emergency Electrical Systems(C): delete 'attendant's station'. There are no attendant's stations in these facilities.

Based on the above, the Department requests final promulgation of the amendments as revised based on the public comment.